CLINICAL AND RADIOGRAPHIC ASSESSMENT OF SOCKET AUGMENTED AND NON AUGMENTED MAXILLARY SINGLE EDENTULOUS SITE RESTORED USING SINTERED POROUS SURFACED DENTAL IMPLANT (ENDOPORE®) - A COMPARATIVE STUDY

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BRANCH VI

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CERTIFICATE

This is to certify that this dissertation titled "CLINICAL AND RADIOGRAPHIC ASSESSMENT OF SOCKET AUGMENTED AND NON AUGMENTED MAXILLARY SINGLE EDENTULOUS SITE RESTORED USING SINTERED POROUS SURFACED DENTAL IMPLANT (ENDOPORE®) - A COMPARATIVE STUDY" is a bonafide record of work done by **Dr. MD ABDUL RAHIM AKBAR,** during his postgraduate study period 2009-2012.

This dissertation is submitted to the **TAMILNADU DR.M.G.R MEDICAL UNIVERSITY** in partial fulfilment for the degree of **MASTER OF DENTAL SURGERY, BRANCH – II PERIODONTICS**. It has not been submitted (partial or full) for any other degree or diploma.

Dr. T.S.S. Kumar, MDS.,
Professor and Head of the Department
Department of Periodontics
Ragas Dental College & Hospital
Chennai

Dr. G. Sivaram, MDS.,
Associate professor and guide,
Department of Periodontics
Ragas Dental College & Hospital
Chennai

Dr. S. Ramachandran, MDS.,
Principal,
Ragas Dental College & Hospital, Chennai.

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LIST OF ABBREVIATION

SPS	-	Sintered Porous Surfaced
CEJ	-	Cemento Enamel Junction
DFDBA	-	Demineralised Freeze Dried Bone Allograft
FDBA	-	Freeze Dried Bone Allograft
HA	-	Hydroxyapatite
LA	-	Local Anaesthesia
CBL	-	Crestal Bone Level
PD	-	Probing Depth
GP	-	Gingival Phenotype
PH	-	Papilla Height
WKG	-	Width Of Keratinized Gingiva
IBL	-	Implant Bone Level
IOPA	-	Intra Oral Peri Apical Radiograph
OPG	-	OrthoPantomoGram

ABSTRACT

BACKGROUND

To restore a single edentulous site with a Dental implant has become a viable option in modern dentistry. The dental implants placed in pristine ridges have shown long term success in terms of function and esthetics. But such pristine ridges have almost become a myth. Mostpatients report with previous traumatic history or with deficient alveolar ridge as an iatrogenic factor. Hence, indicated for augmentation prior to replacement.

The purpose of this study is to assess the clinical and the radiological changes that could occur in the previously socket augmented site in comparison with non augmented maxillary single edentulous site after placement ofsintered porous surfaced dental implants (ENDOPORE®).

MATERIALS AND METHODS

A total of 14 systemically healthy patients irrespective of gender within the age group of 20 - 55 years, who required replacement of single edentulous site in maxilla with Dental implant were enrolled in this study. Among them 7 patients had previously socket augmented maxillary single edentulous sites and the other 7 patients had adequate ridge. Pre-operative diagnostic evaluation was done clinically, radiographically using intra oral peri apical radiographs and orthopantomograph and also with Dental study model as required.

Two stage endosseous Dental implant procedure was performed under local anesthesia using the Sintered porous surfaced Dental implants (ENDOPORE®) with its standard press-fit protocol.

The clinical parameters such as the width of the keratinized gingiva and gingival phenotype and were assessed at baseline, 3rd month and 6th month along with the crestal bone level which was assessed radiographically. All these clinical and radiographical values obtained during the healing period were evaluated statistically using student t test. Following the completion of 6 month healing period all patients received the Implants prosthesis and assessed further on regular recall visits.

RESULTS

No clinical or radiographical complications were observed during or after the surgical procedure. All implants placed in this study healed uneventfully with no inflammatory signs and symptoms during initial six months healing period following implant placement. One patient among the control group did not report for 6th month follow up, therefore was not evaluated in the present study.

It was observed that the soft tissue parameters such as the width of keratinized gingiva and the gingival phenotype, showed no statistical difference between baseline, 3rd month and 6th month values.

Both the groups reported an acceptable apical migration of the crestal bone level at the implant site. But these values showed no statistical significance when assessed at baseline, 3rd month and 6th month follow-up period.

CONCLUSION

Within the limits of this study, it would be appropriate to concluded that in maxilla the hard and soft tissue of socket augmented or non augmented sites respond similarly when sintered porous surfaced dental implant (ENDOPORE®) were placed.

However, further controlled clinical trials comparing the delayed implant placement on socket augmented sites with immediate

implant placement in fresh extraction site could be more appropriately studied and large sample size should be executed for effective comparison between augmented and non augmented peri implant site response.

KEYWORDS

Maxillary Single edentulous site, ENDOPORE®, sintered porous surfaced dental implant, socket Augmentation, crestal bone level changes.

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INTRODUCTION

The use of Dental implants in the maxillary anterior region to replace missing teeth is a viable treatment option.[69, 68] Advantages of Dental implant in comparison to other prosthetic modalities are it maintains the residual alveolar bone height, the ability of the patient to have ease in oral hygiene measures, increased longevity, function of the prosthesis and it prevents loss of vital adjacent tooth structure [71]. Hence implants are ideal for patients who do not wish to compromise two adjacent natural teeth on either side for fixed prosthetic replacement of a single tooth.

Following tooth extraction, 3-dimensional hard and soft tissue changes occur leading to loss of residual alveolar bone height and width. This complicates the implant team with an ideal implant position for prosthetic replacement. Hence, preservation of the residual alveolar ridge during tooth extraction is crucial to achieve an optimal esthetic and functional prosthesis. With the advent of Dental implant frequently used as a treatment modality for replacing the missing tooth, it is a prerequisite to preserve and maintain an adequate bone volume for placement and stabilization of Dental implants.

In the anterior maxilla, the buccal plate is often extremely thin and friable, which could constitute for bone resorption following tooth extraction.[58] To minimize this pattern of bone loss, modern surgical techniques such as atraumatic extraction using periotomes and Luxators in combination with socket augmentation procedure using variety of bone grafting materials have been advocated. Among which Xenograft seems to have a higher success rate compared to other alloplastic grafts. Clinical and histological studies have shown that this osteoconductive material is transformed into a native bone over a time period[53,75.]

Several Dental implant systems are commercially available. They are broadly divided, based on the shape and relation to the bony housing. The most widely used Endosseous dental implant system has shown high success rate of about 90-95 % as per literature. Endosseous implants are available in various dimensions. Endosseous implants are further sub grouped in to threaded screw implant systems and cylindrical-press fit systems. The long term clinical success of endosseous implants is primarily influenced by the implant bone interface.

A threaded endosseous implant requires a minimum bone height of 10mm for a successful clinical outcome at the time of implant fixation. The primary reason is to create a larger surface area for osseo - integration (Bone to Implant interface).Surface modifications on the outer surface of the implant have evolved to

create a larger surface area and to promote osseointegration.[13] Other factors which affect the treatment outcome of endosseous implant include implant length, diameter, geometry & surface finish.[50]

Press fit design of non threaded implant which uses the open sintered porous surface geometry of the implants which favors vascularization & hard tissue in growth to achieve osseointegration. This results in a 3 dimensional interlocking of the bone to implant and favors effective transfer of forces including non-axial load achieving implant stability.

The purpose of this study was to compare and clinically evaluate the survival rate of sintered porous surface endosseous implant on augmented and non augmented single edentulous maxillary anterior esthetic zone, which includes incisors, canines and premolars.[37] Over 6 month period of time.

AIMS AND OBJECTIVES

AIM :

Aim of this study was to assess and compare the clinical and the radiographic changes of the peri-implant hard and soft tissue around sintered porous surfaced dental implant (ENDOPORE®) in socket augmented and non augmented maxillary single edentulous site.

OBJECTIVE:

1. To clinically assess the peri-implant soft tissue changes around ENDOPORE® implants placed in maxillary single edentulous site.
2. To radiographically assess the amount of crestal bone loss occurred around ENDOPORE® implant during the healing period.
3. To compare the response of socket augmented sites with that of non augmented maxillary single edentulous sites after placement of (ENDOPORE®) implant.

REVIEW OF LITERATURE

The periodontal therapy aims primarily to maintain the teeth in a state of health, function and appropriate esthetics. However, dental tooth extraction is inevitable due to various factors such as dental decay, trauma, endodontic failures, and even due to some periodontal diseases.

The edentulous site could be restored by removable partial denture, fixed crown and bridge or by using a dental implant. But this decision of replacing the extracted tooth is not dependent on the patient or the dentist factor but it mainly depends on the recipient site in terms of the hard and soft tissue. Even more, when single-tooth replacement is indicated the use of fixed or removable partial dentures usually jeopardize the underlying alveolar process resulting in loss of vital hard and soft tissue around the edentulous site over a period of time.

Since the widespread of endosseous dental implants has expanded the available options for tooth replacement. Implants have been proposed to be the most suitable and predictable treatment option when indicated in replacement of a single edentulous site.

Endosseous dental implants are mostly threaded screws made of titanium or one of its alloys (e.g. Ti-6Al-4V). The majority of

threaded implants are cylindrical and popular among them are the tapered shapes that resemble closely to tooth roots providing optimal stress transfer into crestal bone. But with the recent advent various macroscopic body design like cylindrical, threaded, perforated, solid, hollow, or vented; with various microscopic surface designs like smooth, non-coated, coated or textured are available as single-piece and two-piece forms and in a variety of biocompatible materials.

Implant geometry, a key factor that will affect the type of bone-to implant surface interface which is responsible for osseointegration. Most threaded implants achieve integration by planar bone-to-implant surface contact and this does not provide resistance to off-axis tensile forces the resulting stresses will be greatest in bone next to the most coronal implant thread tips. This resultant high localized compressive stresses can lead to micro-fractures in crestal bone followed by resorption. Coinciding with the fact that crestal bone loss with traditional threaded implants occurs in the first year of function.

Unlike most threaded implant designs, sintered porous-surfaced dental implants achieve osseo integration in a 3-dimensional bone in-growth and attain mechanical interlocking with the porous surface region formed by sintered beads. This type of bone-to-implant interface is able to provide resistance to

interfacial tensile (upstream) forces. As a result, there is a more uniform stress distribution around the implant periphery with transverse force components being transferred to crestal bone at all implant aspects. This reduces the likelihood of micro-fracturing and resorption of crestal bone to a greater extend.

FACTORS INFLUENCING CRESTAL BONE LOSS

PATIENT RELATED FACTORS

Bone undergoes a constant phase of physiologic remodeling. **Bartee B.K (2001)**[10] in a review stated that alveolar ridge resorption is an unavoidable consequence of tooth extraction. While the extent and pattern of resorption is variable among individuals leading to progressive loss of ridge contour. So over a long term, prosthodontic complication, loss of function, and inadequate bone for the placement of dental implants may result.

The long-term osseointegration of dental implants also relies on placement within bone that has adequate trabecular density, ridge height and width. **Marx R.E (1998)** [52] suggested that a ridge that is too narrow i.e. less than 5mm will be unable to accommodate standard 3.75mm diameter implants.

IMPLANT RELATED FACTORS

IMPLANT LENGTH AND DIAMETER

Both length and diameter of dental implants may influence marginal bone loss. **Kong et al (2008)** [49] evaluated the factors influencing marginal loss with machine-turned threaded implants functioning in partially edentulous patients for as long as 15 years. He suggested that longer implants lost more crestal bone because they were more likely to have been placed in sites of predominantly alveolar bone rather than basal bone, the latter being more resilient to resorption. **Rokni et al (2005)** [66] reported a similar negative correlation between crestal bone loss and implant length with sintered porous-surfaced, press-fit implants after 5 years of function. Long implants (9 or 12mm) had significantly greater crestal bone loss (0.2 mm more) than short implants (5 or 7mm).In contrast to the short threaded implants which suffer more crestal bone loss than longer ones. The implant length may also influence the outcome of implant. For every 3mm increase in length, the surface area of a cylinder-shaped implant increases by an average of 20-30% ***Carl E. Misch (1999)*** [17] The majority of studies have suggested that implants should be ≥10mm long to ensure high success rates ***Horiuchi K et al (2000)*** [42]

Chung et al (2008) [20] presented retrospective findings of 339 implants with various surface roughness, implant length, and differing implant diameters and demonstrated that increased implant

diameter tends to be associated with reduced crestal bone loss. Finite element model analysis suggested a likely correlation between implant diameter and crestal bone loss with maximum stresses occurring around the implant neck and these stresses are likely to be reduced by increase in the implant diameter.

IMPLANT MACRO DESIGN

The screw implant design develops higher mechanical retention as well as great ability to transfer compressive forces. The screw design not only minimizes micro-motion of the implant but also improves the initial stability, the principal requirement for the success of immediately loaded implants. Additionally, the thread increases the surface area ***Carl E. Misch (1999)***[17] Studies have shown the absence of fibrous tissues at the interface of screw-shaped implants, even though they are loaded immediately after insertion**.** Hence, due to its mechanical retention properties, it is generally recommended to use threaded-type implants ***Kan JY et al. (2003)***[47].

It is also important to note that favorable clinical outcome with cylinder-type implants has been documented when a delayed loading regimen was employed**.**

IMPLANT MICRO DESIGNS

Implant surface Coating

Rough implant surfaces render a significant increase of bone implant contact ***Trisi P et al. (2003)***.[74] The shear strength of implants with a rough surface was shown to be about 5 times as high as that of implants with a smooth surface. Animal and human studies involving immediate loading placement have shown significant differences in implant success ***Corso M et al. (1999)***.[22] The reason for clinical success regardless of implant surface coating may be due to the type of bone utilized in a majority of human trials. As mentioned before, most of the studies have focused on using the anterior mandible, where more dense bone is located. It seems to suggest that the initial mechanical interlocking between threads and dense bone may overcome the beneficial properties that each coating type provides. In fact, peak insertion torque and resonance frequency values demonstrated similar implant primary stability regardless of surface type when placed in type II and type III bone.

CRESTAL BONE LOSS AROUND IMPLANTS

For the evaluation of implant success the vertical bone loss should be less than 0.2mm annually following the first year of service of an implant ***Chou CT et al. (2004)*** [19] Elucidating clearly that Peri-implant bone loss as a phenomenon that occurs even in successful implants.

Various studies both animal and human explored this phenomenon of crestal bone loss among different implant design and techniques

ANIMAL STUDIES

Hermann JS et al. (2000)[40] examined Histomorphometrically crestal bone changes around 59 unloaded rough surface sandblasted and acid-etched (*SLA*) 1- and 2-piece titanium implants in non-submerged and submerged technique randomly placed in edentulous mandibular areas. Concluded that the crestal bone changes occur during the early phase of healing after implant placement. Furthermore, these changes are dependent on the surface characteristics of the implant and the presence/absence as well as the location of an interface (*microgap*). Crestal bone changes were not dependent on the surgical technique (*submerged or non-submerged*).

Assenza B et al. (2003)[08] determined the presence and number of osteoclasts in peri-implant bone in loaded and non loaded implants in order to determine that loading per se could be a contributing factor in peri-implant bone resorption. At the end of 12 months the number of osteoclasts found at the crestal bone in the first 3mm from the implant surface had no statistically significant differences were observed between the control and test implants.

They concluded that loading does not seem to have a relevant importance on the osteoclast activation in peri-implant bone.

Quinlan P et al (2005)[60] determined whether early and immediate loading of dental implants in sand-blasted, large-grit, acid-etched (*SLA*) surfaced implants. With different loading times 3 months (*group A*), 21 days (*group B*), 10 days (*group C*), and 2 days (*immediately*) (*group D*).No clinical failures of integration were noted. The changes in crestal bone heights for groups A, B, C, and D (*means±SE*) were 0.02±0.07mm, 0.30±0.08mm, 0.15 ±0.08mm, and 0.35±0.18mm, respectively. Total bone-to-implant contact for the 4 groups was 69.1%, 71.3%, 74.6%, and 75.2%, respectively ($p > .57$). Under the conditions of this study no statistically significant differences were noted between the 4 different loading protocols for any of the parameters recorded.

HUMAN STUDIES

Pham AN et al. (1994)[56] investigated the radiographic changes in alveolar crestal bone levels adjacent to dental implants prior to and after functional loading. A computer-assisted method was used to measure the percent of bone change (%BC) relative to the shoulder-apex length of the implants at mesial and distal sites. Bone loss adjacent to press-fit implants was significantly higher

than that adjacent to the screw type during PRE, while no difference was found during the post-loading periods.

Bragger U et al (1996)[15] correlated the changes in the peri-implant tissues occurring after functional loading of non-submerged titanium implants and assessed it by radiographic, clinical and mobility measurements. 11 patients with distal extension situations received 18 implants of the ITI Dental Implant System. The data obtained from this small sample of implants demonstrated a wide range of different tissue alterations when using radiographic, clinical and mobility assessments. The parameters of probing attachment level (*PAL)* in combination with radiographic parameters obtained at 1, 3, and 6 months after loading were good predictors for the peri-implant tissue status at 2 years.

Becker W et al. (1997)[12] evaluated the clinical outcomes of 135 implants were placed into 63 adult patients, after placement and restoration of one-step Branemark implants into the maxilla and mandible of completely and partially edentulous patients. Results of this studies had crestal bone changes in mandible and maxilla were statistically and clinically insignificant.

Bragger U et al. (1998)[14] conducted a prospective study with 128 patients by reproducibility of a simple radiographic method for linear measurements of changes in bone levels and to evaluate

changes in crestal bone levels adjacent to non-submerged ITI implants 1 year following the surgical procedure. The age of the patients was not correlated significantly to the amount of bone loss observed. He concluded that methodological limitations existed when evaluating linear bone changes in non-identical radiographs using reference dimensions of the implants. The amount of postsurgical bone loss estimated in other studies was confirmed when using an immediate postoperative radiograph as a baseline.

Randow K et al. (1999)[62] radiographically compared the outcome of oral rehabilitation in the edentulous mandible by fixed supraconstructions connected to implants installed according to either i) a 1-stage surgical procedure and immediate loading (*Experimental Group-EG*), or ii) the original 2-stage concept (*Reference Group-RG*). The analysis of the radiographs from the EG disclosed that during the 18-month observation period the mean loss of bone support amounted to 0.4mm. The corresponding value observed in the RG was 0.8mm.

Weber HP et al (2000)[76] conducted a prospective 5-year study on 112 ITI dental implants to calculate implant success by life table analysis and also to evaluate the correlation between observed bone level changes with clinical parameters as measured by suppuration, plaque indices, bleeding indices, probing depth, attachment level and mobility. The overall success rate after 5 years in service was

99.1%, while after 6 years it was reduced to 95.5% due to the fracture of 3 implants in 1 patient. mean crestal bone loss experienced during the first year was 0.6mm followed by an annual yearly loss of approximately 0.05mm.

Barboza EP et al. (2002)[09] evaluated the crestal bone levels adjacent to submerged and exposed unloaded dental implants during the initial healing phase. In addition, the microbiota around exposed implants were studied. All patients showed more crestal bone loss around exposed dental implants compared to submerged implants. Prevotella sp., Streptococcus beta-hemolyticus, and Fusobacterium sp. were the microorganisms identified in most of the sites. The initial healing phase follow-up may be critical for implant success.

Becker W et al. (2003)[11] evaluated placement of 4 to 6 implants in edentulous mandibles. The implants were placed between mental foramina for support of non-metal, reinforced, fixed, implant-supported provisional prostheses. A unique method was used to convert existing dentures into fixed, implant-supported appliances. Success rates for the interim and final prostheses were 100%. A simple, possibly cost-effective method of using non-metal reinforced dentures as interim fixed, provisional dentures had been described. The modified denture could function as an interim fixed, implant-supported prosthesis for up to 30 months. Results of x-ray

measurements indicated stable crestal bone levels for up to an average of 15 months.

Carr AB et al. (2003)[18] evaluated the long-term clinical performance of 1-stage dental implant prostheses at a single clinic, emphasizing clinical and demographic characteristics that affect implant survival.

Heydenrijk K et al. (2003)[41] evaluated the feasibility of using a 2-stage implant system in a single-stage procedure and studied the impact of the microgap between the implant and the abutment. Sixty edentulous patients (*Cawood class V or VI*) participated in this study. A standardized clinical and radiographic evaluation was performed immediately after prostheses placement and after 12 and 24 months. Placement of the microgap at the crestal level in 2-stage implants did not appear to have an adverse effect on the amount of peri-implant bone loss at 2 years in this study population.

Kan JY et al. (2003)[47] evaluated the implant success rate on 35 participate peri-implant tissue response, and esthetic outcome of immediately placed and provisionalized maxillary anterior single implants. The patients were evaluated clinically and radiographically at implant placement and at 3, 6, and 12 months after implant placement. The results of this study suggested that favorable implant success rates, peri-implant tissue responses, and

esthetic outcomes could be achieved with immediately placed and provisionalized maxillary anterior single implants.

Ricci G et al (2004)[63] assessed the crestal bone resorption 5 years after loading by conducting a clinical and radiographic evaluation of 112 Frialit-2 implants consecutively placed in 51 patients. The increased survival rate of the implants may be the result of the relatively short functional period as well as the strict and frequent clinical evaluations associated with oral hygiene procedures during the supportive periodontal therapy. Results of the study showed that with strict plaque control, and if the patient follows a regular program of supportive therapy, crestal bone resorption around a 2-stage implant system may be limited.

Schwartz-Arad D et al. (2004)[70] examined the cervical bone loss (*CBL*) and its correlation with implant characteristics and anatomic factors, 1 to 8 years post-implantation of immediate and delayed implants. A total of 381 implants (*144 immediate and 237 delayed*) were placed in 44 edentulous patients (*53 jaws*) for fixed ceramometal restoration from 1989 to 1996. The mean mesial and distal cervical bone resorption of each implant was measured using panoramic radiographs, by an objective examiner using a computerized scanner before second stage surgery and 1 to 8 years (*mean 3.5 years*) follow-up. The length of the implant served as an internal standard. Total CBL was 0.78±1.22mm. There was a

significant difference (*p=0.049*) between CBL of immediate implants compared to delayed ones. Implants > 13 mm showed a significantly (*p<0.001*) lower CBL than shorter implants. Hydroxyapatite-coated implants had a higher CBL (*p<0.001*) compared to commercially pure titanium implants (*p<0.001*). The CBL of maxillary implants was higher than mandibular implants (*p<0.001*). They concluded that cervical bone loss around dental implants is influenced by location, coating, length, and implant timing.

Romanos GE et al. (2005)[67] demonstrated histologic analysis of retrieved, clinically stable immediately loaded implants with different implant designs and surfaces. A total of 29 implants with different implant designs and surfaces were retrieved from patients who were treated with implants using an immediate loading protocol and fixed immediate restorations placed the same day after surgery. A high bone-to-implant percentage of 66.8% *(±8.9%*) was found in the examined retrieved implants.

Robert A. Jaffin et al (2007)[64] evaluated the radiographic bone levels adjacent to implants placed in fresh extraction sockets (*ESs*) and compared to bone levels adjacent to implants placed in native bone (*NB*) at a time interval of 5 years. A total of 139 implants, 42 ES and 97 NB, placed in 17 patients were evaluated. They concluded that the combination of ES and NB implants can be

immediately loaded with a fixed full-arch prosthesis and remain stable for greater than 5 years. The bone loss adjacent to these implants is similar to that seen surrounding those placed and restored using traditional protocol.

CRESTAL BONE LOSS IN NON LOADED IMPLANTS

Studies have given attention to the crestal bone changes during the period immediately following implant insertion. ***Bragger U et al. (1998)***[14] reported median distances of bone from the implant shoulder and median changes over the first year after implant insertion. Median levels were between 2 and 3mm below the shoulder, with median changes of slightly less than 1mm. Mean levels and changes would be expected to be somewhat greater than these median values. ***Pham AN et al. (1994)***[56] also found significantly higher bone loss rates in the period immediately following placement (with a rate of 1.28% of implant length per month) than in the post-loading intervals. They also found a difference in bone loss rate between the press-fit and screw-type implant designs.

SOCKET AUGMENTATION AND ITS INFLUENCE ON CRESTAL BONE LOSS AROUND IMPLANTS

The alveolar process is a tooth-dependent tissue that is developed in conjunction with tooth eruption. The topography is determined by the form of the teeth and the axis of eruption.

Subsequent to tooth extraction, the alveolar ridge undergoes resorption and atrophy, thus exhibiting a wide range of dimensional changes among individual patients. Reporting as early as 1941 by **Rodgers et al (1941)** [65] described resorption of the alveolar bone housing that result in changes of the alveolar bone morphology after extraction frequently resulting in excessive loss of both height and width of bone. But these changes did not follow a consistent pattern, studies by **Sobolik et al (1960)**[73] also stated that normal post-extraction healing response of an intact alveolar socket is resorptive. And the greatest amount of bone loss is in the horizontal dimension and occurs on the facial aspect of the ridge.

To minimize bone resorption, Atraumatic extraction techniques with socket augmentation, using a variety of particulate bone graft materials with and without membrane barriers were reported. These preservation techniques demonstrated significant reduce of alveolar ridge dimensional changes.

Among the various graft materials used few were successful as **Artzi and Nemcovsky** used a deproteinized bovine bone mineral (DBBM) as a socket site filler material to maintain ridge configuration, without applying an occlusive membrane. New bone formation was observed in all histological specimens. This author had similar reporting's on various animal studies **Artzi et al (2000)**[06] reported Bone fill of 82.3% in augmented sited 9 months

post operatively using Porous bovine bone mineral *(Bio-Oss®, Geistlich). H*istomorphometric measurements showed an increase of mean bone tissue along the histological section from 15.9% in the coronal part to 63.9% apically.

Artzi et al (2001)[07] investigated Histochemically healed sockets grafted with Porous bovine bone mineral *(Bio-Oss®, Geistlich)* which reveal newly formed bone encircled and adhered to the grafted material in most specimens. An average of 17.1% osseous tissue with 1:12.9 lamellar/woven ratio in the superficial areas, whereas 63.9% osseous tissue, with a lamellar/ woven ratio of 1:1.7 was observes in deep areas of the specimen.

Further animal studies were conducted by **Indovina A, Block M.S (2002)[44]** evaluated the healing response of 3 bone substitutes in canine extraction sites. No significant difference as noted in shape of the ridges between groups. The untreated control and the BioOss *(Osteohealth)* were similar with bone filling in most of the extraction sites.

Studies on Human subjects on socket healing reported by **Froum et al (2004)[32]** investigated the effect on extraction socket healing when an absorbable hydroxyapatite (AH) and a nonabsorbable anorganic bovine bone mineral (ABB) covered with either an acellular dermal matrix allograft (ADMA) or expanded

polytetra fluoroethylene (ePTFE) membrane barrier They concluded that ADMA-covered sites resulted in more vital bone present 6 to 8 months post socket treatment than obtained in the ePTFE-covered sites regardless of bone replacement materials used.

Nevins et al (2006)[54] compared the fate of the buccal wall of extraction sockets of teeth with prominent roots that received a deproteinized bovine bone mineral *(Bio-Oss, Osteohealth)* with sockets that received no osteogenic material. CT scan results revealed that those sockets treated with Bio-Oss demonstrated a loss of less than 20% of the buccal plate

Molly L et al (2008)[53] presented a case series to evaluate bone formation histologically and biomechanically in extraction sites following implantation of a synthetic sponge based on polylactic-polyglycolic acid technology (FIS*)(Fisiograft),* BPBM (*Bio-oss®, Geistlich*) and a natural coral derivative physically and chemically transformed into a calcium carbonate ceramic *(Biocoral) and* were covered with polytetra fluoroethylene device (*Goretex).* The percentage of biomaterial was 5.6% for FIS, 20% for BPBM and 12.0% for COR. Histologically, new bone apposition was seen on BPBM particles. FIS sites showed similar in growth of blood vessels and osteocytes as empty controls.

Bio-Oss®Collagen

As with Bio-Oss®, the mineral structure of Bio-Oss® Collagen a highly porous material possessing a large internal surface area, and functions as an effective scaffold for bony in-growth and cell adhesion. The collagen component enables convenient handling and facilitates formation of a stable blood clot. Collagen acts as a natural ligand for keratinocytes and fibroblasts during wound healing. Suspended within a 10% collagen matrix, the Bio-Oss® particles are highly stabilized when placed within a defect site. Well contained within the socket and almost completely eliminates particle migration from the site thereby supporting the buccal contour of the alveolar ridge and stabilizing the blood clot.

Nevins M et al (2003)[55] evaluated the radiographically and histological response to *Bio-Oss®Collagen* when used alone or in combination with *BioGide* bilayer collagen membrane for the treatment of intrabony defects (5-7mm). Reduction in probing depth and gain in clinical attachment level were observed for both treatment protocols. The histological evaluation demonstrated that bio-Oss collagen has the capacity to induce regeneration of the periodontal attachment apparatus when placed in intrabony defects.

Zitzmann et al (2003)[78] evaluated the effect of a bioresorbable collage membrane *(Bio Gide)* and composite bone graft material deproteinized bovine bone mineral with collagen

(BioOss® Collagen, Geistlich) in periodontal regeneration of angular bone defects. Results were that residual PD and CAL were reduced to 3.3mm and5.6mm and CAL gain was 3.2mm 24 months postoperatively. Radiographic defect reduction was 4.0mm after surgery and 2.2mm after 24 months.

Hartman et al (2004)[38] evaluated anorganic bovine-derived xenograft (*Bio-Oss® Collagen, Osteohealth*) in the treatment of human periodontal defects. Three of the eight defects examined received a resorbable collagen barrier (*Bio-Gide*) in addition to the bone graft. Six months post surgery majority of sites showed a favourable clinical response with respect to probing depth reduction and clinical attachment gain. Histologic analysis demonstrated new bone, cementum and periodontal ligament coronal to the reference notch in two of the eight specimens. Two sites demonstrated new attachment, and four showed a long junctional epithelium.

Jung et al (2004)[45] analysed the graft enhanced soft tissue healing during initial phases after tooth extraction. The soft tissue punch technique (for harvesting epithelialized free gingival graft) used successfully led to biologic and esthetic integration of the graft (*DBBM integrated in 10% collagen –Bio-Oss®Collagen*) into the local host tissues.

Cardaropoli G (2005)[16] in an experimental study in dog evaluated the influence of different biomaterials on the healing of surgically produced bone defects. In defects augmented with *Bio-Oss® Collagen Geistlich* the biomaterial occupied a substantial portion of the tissue volume. 85% of the periphery of the Bio-Oss particles were found to be in direct contact with the newly formed mineralised bone. They concluded that the Bio-Oss Collagen augmented defects exhibited less wound shrinkage than the non-augmented defect.

Araujo M.G et al (2008)[03] experimented the effect of Bio-Oss® Collagen in healing of extraction sockets in dog. From results of histomorphometric analysis they concluded that the presence of Bio-Oss Collagen failed to inhibit the process of modelling and remodelling that took place in the socket walls following tooth extraction. However it apparently promoted denovo hard tissue formed particularly in the cortical region of the extraction site.

Araújo M.G, Lindhe J. (2009)[05] evaluated the long-term effect on hard tissue formation and the amount of ridge augmentation that can occur by the placement of a xenogenic graft *(Bio-Oss® Collagen)* in extraction sockets of dogs compared to contralateral non grafted site. The placement of Bio-Oss® Collagen in the fresh extraction socket served as a scaffold for tissue modelling but did not enhance new bone formation. In comparison

with the non-grafted sites, the dimension of the alveolar process as well as the profile of the ridge was better preserved in grafted sites.

Ackermann K.W et al (2009)[01] in a retrospective case study on extraction site management using *Bio-Oss® Collagen* observed that the soft tissue volume and the contour were largely preserved at all sites, irrespective of the initial defect morphology. The author also reported that Bio-Oss® Collagen presented with predictable preservation of the soft tissues, favourable healing characteristics, and easy handling of the material.

Araújo et al (2010)[04] analyze d the processes involved in the incorporation of *Bio-Oss® Collagen* in host tissue during healing following tooth extraction and grafting. Histomorphometric analysis revealed that the biomaterial was first trapped in the fibrin network of the coagulum. Neutrophilic leukocytes polymorphonuclear (PMN) cells] migrated to the surface of the foreign particles. In a second phase the PMN cells were replaced by multinuclear TRAP-positive cells (osteoclasts). The osteoclasts apparently removed material from the surface of the xenogeneic graft. When after 1-2 weeks the osteoclasts disappeared from the Bio-Oss granules they were followed by osteoblasts that laid down bone mineral in the collagen bundles of the provisional matrix. In this third phase the Bio-Oss particles became osseointegrated.

IMPLANT STABILITY IN SOCKET AUGMENTED BONE

The ultimate goal socket augmentation procedures are successful implant placement. Several studies have examined the long term stability of implants placed in grafted bone.

Fritz et a1 (2001)[31] evaluated the success of implants in regenerated bone from a Histologic perspective Implants were placed in monkeys in both native and regenerated bone and then loaded with a fixed prosthesis for one year. Bone to implant contact showed no significant difference between the implants in native bone (59%) and the implants in regenerated bone (65%).

Fiorellini & Nevins in (2003)[31] Reported a high level of predictable implant survival in sites treated by GBR or preservation techniques. These survival rates are similar to those of implants placed in native bone. Based on the results of these studies it is clear that implants placed in regenerated bone are just as successful as those placed in native bone

Zafiropoulos et al (2010)[77] in a retrospective study evaluated 241 single implants of tapered and cylindrical screw type in fresh and regenerated extraction sockets. Implants were categorised into immediate placement, delayed placed, immediate non-loading and delayed loading. The authors concluded that the type of implant,

position and timing of implant did not influence the survival rate of the above treatment methods.

SINTERED POROUS-SURFACED DENTAL IMPLANT.

Maniatopoulos et al (1986)[56] Compared Porous-surfaced design to conventional threaded designs in animal model for the effect of implant design on stabilization.12 month post loading Pull-out test performed indicated increased shear strength for the porous-surfaced implants in contrast to the gradual loss of fixation for the threaded implants. Histological examination indicated the reason for these changes, threaded implants although initially had a mechanical interlocking with bone, developed a fibrous connective tissue capsule that gradually thickened and this was assumed to be due to implant movement. The porous-surfaced implants however became stabilized by bone in-growth and showed more extensive bone formation within the surface pores with time thus presenting a more favorable long term prognosis.

Cox et al and R.M. Pillar et al *(1987)*[23] assessed the migration and orientation of human gingival fibroblasts in relation to the rim of smooth surfaced and porous-coated titanium discs in vitro. The cells migrated from the multilayer onto the smooth surfaced discs forming bridges between them, and orientated along parallel circumferential grooves in the rim of the discs. Cellular bridges were also formed between the porous-coated discs and the

multilayer but, because the cells that migrated onto, and between, the spheres of the porous-coat showed no preferred orientation. These observations suggest that the geometrical configuration of the surface of implants could influence whether a capsule or an orientated fibrous attachment is developed in relation to implants in vitro.

R. Todescan et al (1988)[61] Evaluated Endosseous, Porous-surfaced Implant System in the animal models after a functional period of eight months they modified apical 1/3 of the transgingival collar to porous surface in an attempt to gain in-growth and attachment of gingival connective tissue The qualitative histological data confirmed that while such attachment to the collar did occur for some implants, in the majority of implants (22 of 32) the porous region of the collar became contaminated with bacteria plaque, resulted in implant failure Statistical analyses of the quantitative histological data indicated that there were no significant differences in surface contact of bone with the porous implant surface during the initial healing interval.

R.M. Pilliar et al *(1991)* [59] assessed the Bone remodeling around three different endosseous dental implant designs placed in dog mandibles. The three designs investigated were (a) threaded (C.P. titanium), (b) fully porous-coated (titanium alloy), and (c) partially porous-coated (titanium alloy). Post functionally after 72

weeks crestal bone loss occurred for both the threaded and partially porous-coated implants while no significant bone loss was seen with fully porous-coated implants. It is suggested that these observed differences are a result of the different stress states that develop in bone surrounding the three designs underlying the importance of implant design on bone remodeling.

Deporter DA et al (*1999*)[25] Reported clinically the Use of a Tapered, Porous-Surfaced Dental Implant in Combination with Osteotomes to Restore Edentulism in posterior Maxilla As it is the more difficult arch to restore because of hurdles such as low bone density, narrow buccopalatal width, minimal bone height, and proximity to the maxillary sinus. The use of short, tapered, porous-surfaced implant and a placement protocol using hand osteotomes rather than surgical burs have solved most of these problems.

P.A. Watson et al (*1986*)[27] reported histological assessment of the initial healing response following implantation into the dog mandible of a porous-surfaced, titanium alloy endosseous dental implant. Two implants were placed in edentulous areas on each side of the mandible of each dog and covered with a full-thickness mucoperiosteal flap. The implant sites on one side of the mandible were allowed to heal for four weeks, while those on the other side were allowed to heal for eight weeks before the animals. Histological specimens were obtained and assessed both

qualitatively and by computer-assisted morphometry. The histomorphometric measurements revealed that bone ingrowth had reached a plateau by four weeks of initial healing.

A comparison of the total surface area between 1st generation-treaded Dental implant and 2nd generation SPS Dental implant – courtesy D.A. Deporter[28]

D.A. Deporter et al (1990)[28] compared Porous-Coated vs Threaded Dental Implants in animal model The histological findings after an 18-month trial they estimated the length of implant surface in direct contact with bone on each aspect of each implant. However, when the absolute contact length was related to the corresponding vertical bone height, significant differences were observed, the absolute contact length being greater for any given bone height for the porous-coated design. Taken together, the data suggest that shorter implants may be used with the porous-coated design.

A.H. Melcher et al (*1986*)[35] Histologically Investigated the Healing Response Adjacent to Porous-surfaced Titanium Alloy Oral Implants in Dogs **p**orous-surfaced designs have demonstrated osseous fixation through in growth. The conditions necessary for bone in growth to occur are: initial implant stability, i.e., an initial healing period during which the implant is not in function or subject to any gross mobility; a sufficiently large pore size to permit bone in growth; and use of a biocompatible material. The recommended pore size is in the range of 100 to 400 μm as this encourages the in growth of bone rather than fibrous connective tissue.

R. Todescan et al (*1988*)[61] developed a small animal model to investigate materials and implant designs intended for use as immediate replacements for extracted teeth. The effect of biological graft materials such as mineralized bone powder, demineralized bone powder, and collagen (Zyderm) on healing in relation to an endosseous porous-coated Co-Cr alloy implant placed into an extraction socket the resultant report is that Zyderm produced significant improved healing over the demineralized bone powder and implant alone.

R.M. Pilliar et al (*1991*)[59] studied The Effect of Partial Coating with Hydroxyapatite on Bone Remodelling in Relation to Porous-coated Titanium-alloy Dental Implants in the Dog for inhibition of crestal bone resorption due to stress shielding and

disuse atrophy. The plasma-sprayed HA coating resulted in significantly greater bone height formation and maintenance next to the coronal portion of the implant compared with non-HA-coated implants of similar design after 72 weeks of function.

Pharoah M et al (1992)[24] reported the findings Clinical Trial of a Partially Porous-Coated, Endosseous Dental Implant in Humans after 6 Month post loading the results indicated that porous-coated implants could be shorter than threaded implants because of the increased surface area per unit length of implant available for bone in growth with the porous design. This report is concerned with an experimental protocol and 6 month results from the first human trial in which this partially porous-coated implant system has been used to treat completely edentulous patients, the majority of whom had severe mandibular alveolar ridge resorption.

D.A. Deporter (1992)[26] Reported 2 Year Human clinical trial results of Partially Porous-coated Dental Implants in anterior mandible of 52 edentulous individuals and used them to support mandibular overdentures showed that crestal bone remodeling begin to level off by 12 months, and is not progressive beyond the coronal-most limit of the porous coat. No significant changes from baseline in blood levels of Ti, Al and V were observed.

MATERIALS AND METHODS

Patient Selection

The patients selected for this study were from the Out Patient Department of Periodontics, Ragas Dental College and Hospital, Chennai. Patients who required replacement of a single missing tooth with Endosseous dental implant in maxillary anterior aesthetic zone were selected. They were grouped as, Group A with patients who have undergone socket augmentation procedure using a Xenograft at the implant site at least six months prior to the commencement of the study. And group B with patients who had adequate ridge dimensions at the edentulous area and are willing to undergo replacement of their missing tooth with two stage Endosseous dental Implant.

All patients were explained about the advantages and disadvantages of the proposed Dental implant treatment plan. Oral and written informed consent was obtained prior to Implant placement and followed up over a 6 month time period.

INCLUSION CRITERIA

1. Patients aged between 20 to 55 years, irrespective of gender.
2. Patients whose full mouth plaque and Gingival bleeding scores less than 20% were enrolled into the study.

3. Patients with good oral hygiene and without any active periodontal disease were selected.
4. Patients with pre augmented socket at the implant site using xenograft material (Bio-Oss® collagen) six months prior were enrolled in the study group.
5. Patients with non augmented single edentulous implant site with adequate ridge dimension width and length.
6. Radiographic evidence of crestal bone height less than or equal to 3mm from the cemento-enamel junction of the adjacent tooth.

EXCLUSION CRITERIA

1. Patients with any systemic condition that can affect the outcome of the implant therapy.
2. Patients with existing periodontal disease or patient undergoing active periodontal therapy.
3. Patients with previous history of allergy to the material or medication to be used in this study.
4. Pregnant and lactating women.
5. Patients with present history of smoking / pan chewing habit.
6. And patients with parafunctional habits were excluded from the study.
7. Radiographic evidence of any peri-apical pathology around the implant site.

A total of 14 patients who satisfied the inclusion criteria were enrolled in this study, and the patients were grouped as

Group A (Socket augmented group) – **7** Patients with pre-augmented socket at the implant site using xenograft material (Bio-Oss® collagen) six months prior.

Group B (Non-Augmented group) – **7** patients with non augmented single edentulous implant site with adequate ridge dimension (in terms of width & height).

And these 14 patients went througha two stage implant protocol using sintered porous surfaced Dental implant **ENDOPORE®** and were followed up for a period of 6 months and assessed for clinical and radiographic parametric changes.

ARMAMENTARIUM

1. Dental mouth mirrors – 2 no.
2. Explorer – 1 no.
3. Tweezers – 2 no.
4. Periodontal UNC-15 Probe (coded 1-15 mm) – 1 no.
5. 2ml Disposable syringe (dispovan) – 1 no.
6. 1:80,000, 2% Lignocaine (lignox, warren) – 1 bottle.
7. Bard Parker handles no. 3 with No.15 blade – 2 no.
8. Periosteal elevator – 1 no.

9. Toothed and Non toothed Tissue forceps – 1 each.
10. Cotton swabs & Gauze strips.
11. Kidney tray – 2 no.
12. Saline bowl and 10ml irrigation syringe – 2 no
13. Normal Saline 500ml - 1 bottle.
14. Plastic suction tip – 1 no.
15. Dappen Dish – 1 no.
16. Suture material - synthetic, non resorbable 3-0 black silk.
17. Needle holder – 1 no.
18. Suture cutting scissors – 1 no.
19. ATR 2000 Physiodispenser
20. ANTHOGYR® 1:20 implant hand piece
21. Endopore® Dental Implant
22. Endopore® Dental Implant Kit and osteotomes - 1 no.

Clinical parameters assessed during the study period were.

1. Width of Keratinized Gingiva (WKG).
2. Gingival Phenotype (GP).
3. Papillary Height (PH).
4. Probing Depth (PD).

Radiographical parameters assessed during the study period were.

1. Crestal Bone Level (CBL).
2. Implant Bone Level (IBL).

All parameters were recorded in millimetre (mm) scale and assessed at 3 time interval (from placement of the dental implant till it was loaded) namely- baseline (0M), 3rd month (3M) and 6th month (6M).

ACLINICAL PARAMETERS

WIDTH OF KERATINIZED GINGIVA (WKG) in mm

Width of keratinized tissue at the edentulous implant site was measured using a periodontal UNC-15 colour coded probe. It was measured from crest of Gingival Crestal Margin (GCM) to the Muco-Gingival Junction (MGJ) at 2 reference points, mesial and distal using a customized acrylic stent for standardization and reproducibility of the value during recall visits

GINGIVAL PHENOTYPE (GP) in mm

The thickness of gingival tissue was measured on the buccal aspect of the single edentulous site at 4mm from the gingival margin using a 20 size reamer with a stopper at pre operative and post operative period.

The phenotypes were classified as

1- Thin gingival phenotype < 2mm.

2- Thick gingival phenotype ≥ 2mm.

PAPILLARY HEIGHT (PH) in mm

The mesial and distal papillary height were measured at the proximal sides to the edentulous region from the base of the papilla to the tip. By using to periodontal probes, one placed across the cement enamel junction of the tooth at either side and the papilla height is measured from the first probe to the coronal most tip op the proximal papilla on both mesial and distal side to the nearest of 0.5 mm

Measuring mesial papillah

Measuring distal papillah

PROBING DEPTH (PD) in mm

The probing depth of the teeth adjacent to the single edentulous site were measured using a heat cure acrylic stent place on the adjacent tooth using a calibrated UNC -15 probe, the distance from the stent to the base of the sulcus is measured and recorded as “A“. the stent to the inter dental papilla is measured and recorded as

"B". the papilla height is measured by subtracting "A-B" and this value is recorded to a nearest of 0.5mm at baseline, 3rd month and 6th month respectively.

RADIOGRAPHIC EVALUATION

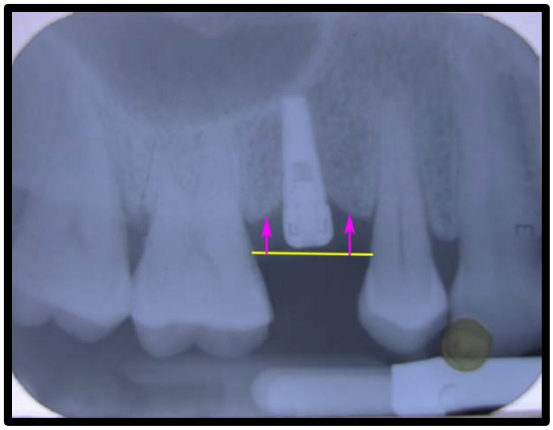
Orthopantomograms (OPGs) were taken during the initial visit to evaluate the hard tissue at the edentulous site and the patient who satisfied the inclusion criteria were enrolled in the study as Augmented and Non -augmented.

Augmented group consisted patients who underwent socket augmentation procedure using Xenograft in a block form, following Atraumatic extraction and completed a satisfactory healing period of 6 months. All the patients who participated in this clinical study were subjected to intraoral periapical radiograph using a standardized geometry and radiation protocol at pre operative, post operative and during recall period.

All the standardized intraoral periapical radiographs were converted in to a digital image using an HP image scanner and these digitalized images were enhanced using computerized imaging software (Adobe Photoshop 7) for further evaluvation.

CRESTAL BONE LEVELS (CBL)

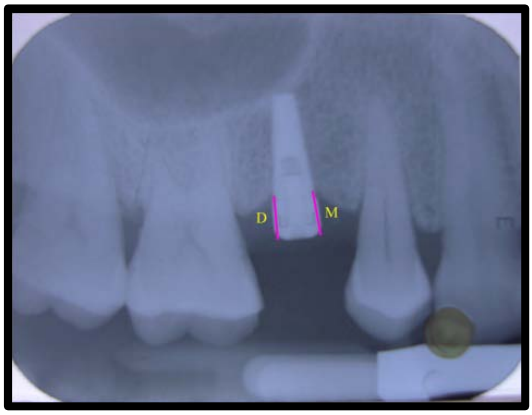
Changes were measured at implant site by using an arbitrary line connecting the cemento-enamel junction of the adjacent tooth. And by measuring the distance from the arbitrary line to the crestal module of the alveolar bone at both mesial and distal aspect along the line angles of the adjacent tooth perpendicularly.



These values were recorded at baseline (BO) before implant placement, 3rdmonth (3M) and 6th month (6M) after implant placement and were expressed numerically to closest of 0.5mm.

BONE TO IMPLANT LEVEL (BOI)

Bone to Implant level was calculated by measuring the distance from the implant collar to the appropriate first bone to implant contact region at mesial and distal aspect. These values were recorded and evaluated at 3rd month (3M) and 6th month (6M) after implant placement and were expressed numerically closest of 0.5mm.



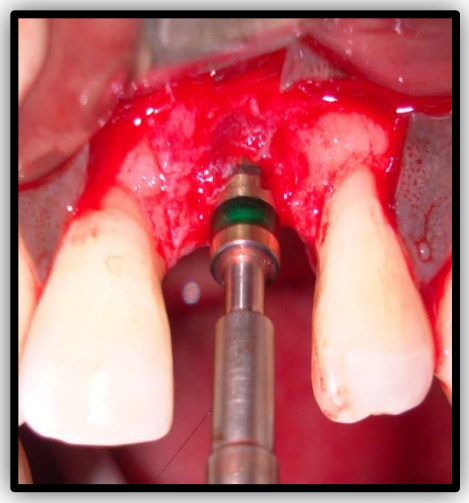
SURGICAL PROCEDURE

After assessing the pre-treatment records, the patient was prepared for implant placement. Strict asepsis was followed during the procedure.

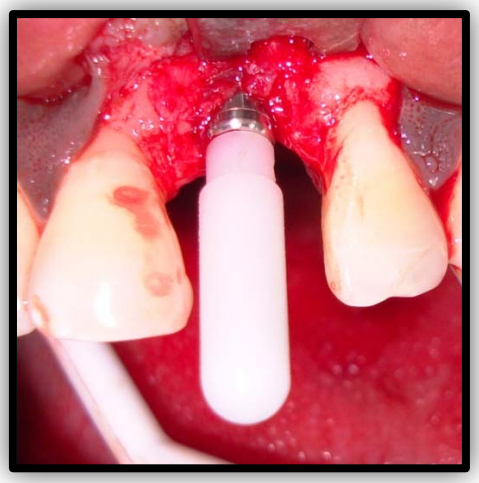
1. Under local anesthesia full thickness mucoperiosteal flap was raised by giving a crestal incision involving the papillae of the adjacent teeth. Once the alveolar ridge was exposed the optimal implant site was marked using a pre-surgical prosthetic guide. The cortical perforation done using a 2.3 mm round bur at 1200-1500 rpm with copious external saline irrigation.
2. Appropriate depth was drilled using the pilot drill at a speed of 1000-1500 rpm with copious internal and external sterile saline irrigation.
3. A paralleling pin was placed into the osteotomy site to check the proper angulations of the future implant with the adjacent teeth and the opposing occlusion. A confirmatory radiograph was taken.

4. Sequential drilling was done at the osteotomy site for the required diameter and length of the implant to be placed. Once the final drilling is complete the trail fit gauge is placed

in to the osteotomy site to assess the primary stability of the implant to be placed.



5. The sintered porous surfaced dental implant Endopore® of appropriate dimension was carefully removed from the sterile packaging and pressed into the bleeding site.
6. The implant was driven into its final position by repeated firm taps using the punch tip and a surgical mallet until the implant collar was flushed with the bone crest.



7. To prevent cover screw loosening the hex driver was used with digital pressure to tighten the cover screw.
8. The flap margins were then repositioned and a tension free primary closure was obtained using 3-0 black silk.
9. The final position and angulations of the implant was confirmed using to intraoral periapical radiograph.

POST OPERATIVE CARE

Post operatively analgesics and antibiotics cover were given for a period of 5 days. Amoxicillin 500 mg 3 times a day for 5 days, Ibuprofen + Paracetamol combination 3 times a day for 3 days and later if required. Chlorhexidine mouth wash was prescribed throughout the healing period.

Patients were restricted to a soft diet and advised to avoid the use of any removable prosthesis. The sutures were removed 10 days post operatively and were examined for any post operative complications.

All patients participated in this study did not show any complications or allergic reactions and were evaluated for the soft and hard tissue parametric changes and were followed up at 3rd and 6th month after Implant placement.

There after the implants were loaded successfully and followed up further

.

PROFORMA

Out Patient No: **Date: / /**

Name: **Age/Sex:**

Address: **Contact No.**

E-mail: **Mobile no:**

CHIEF COMPLAINT:

HISTORY OF PRESENTING ILLINESS:

PAST DENTAL HISTORY:

MEDICAL HISTORY:

DRUG ALLERGY:

HABITS	**frequency**	**Duration**
Smoking:		
Alcohol Consumption:		
Betel Nut Chewing:		
Brushing:		
Others:		

CLINICAL EXAMINATION & VITAL SIGNS

BP:

Pulse:

State Of Edentulousness:

Missing Tooth:

Jaw Relationship:

Class I ☐ **Class II** ☐ **Class III** ☐

Molar Relation:

Class I ☐ **Class II** ☐ **Class III** ☐

PRE-TREATMENT EVALUATION:

I. Clinical Examination:

Soft Tissue adjacent to the edentulous site:

- **Oral Hygiene:** Good / Fair / Poor.
- **Gingival Phenotype:** Thin/ Thick.
- **Width of Keratinized Gingiva** a)Mesial: b)Distal:
- **Probing Depth:** a)Mesial: b)Distal:

II. Radiographic Evaluation:

- **Presence of any pathological lesion: yes/no.**
- **Crestal bone level** a)Mesial: b)Distal:
- **Bone to implant contact** a)Mesial: b)Distal:**:**

PRE TREATMENT PROCEDURES

Radiographical:

IOPA

OPG

Bone Mapping

Available Bone: **Width x length**

Bone Augmentation Procedures

INVESTIGATIONS:

Laboratory:

Blood Sugar:

Hb:

BT:

CT:

Others:

TREATMENT PLAN:

I. **Total No Of Implants:**
II. **Site Of Implant Placement:**
III. **Size And Dimension Of Implant To Be Placement:**
IV. **Any Adjacent Procedure:**

PARAMETERS

Clinical Assessment	Site	Base Line	3rd month	6th month
Adjacent Probing Pocket Depth (PD) in mm	Mesial			
	Distal			
Width Of Keratinized Gingiva (WKG) in mm	Mesial			
	Distal			
Gingival phenotype (GP) in mm	Buccal			
Papilla Height (PH) in mm	Mesial			
	Distal			

Radiographic Assesment	Site	Base Line	3rd month	6th month
Crestal Bone Level (CBL) In mm	Mesial			
	Distal			
Implant Bone Level (IBL) in mm	Mesial			
	Distal			

INFORMED PATIENT CONSENT

RAGAS DENTAL COLLEGE AND HOSPITAL, CHENNAI.

DEPARTMENT OF PERIODONTICS AND IMPLANTOLOGY

Patient Name: **Age:** **Sex:**

I have been clearly explained and informed regarding the following surgical procedure to be performed on myself (dental implant placement). In the language known to me (English/Hindi/Tamil) and I have no objection for the treatment and if the treatment shows no anticipated results, I agree to undergo suitable/alternative method for the same. I give my consent for photographs and radiographs to be taken at the beginning, during, and at the end of the study.

PLACE:

DATE: **SIGNATURE OF THE PATIENT**

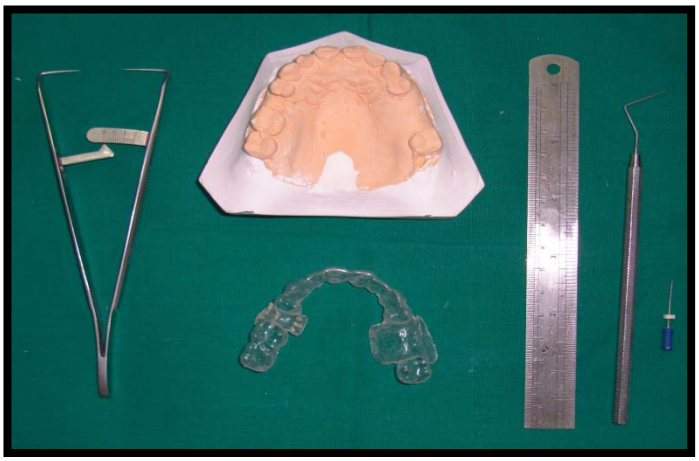
SIGNATURE OF THE P.G. STUDENT.

SIGNATURE OF THE GUIDE.

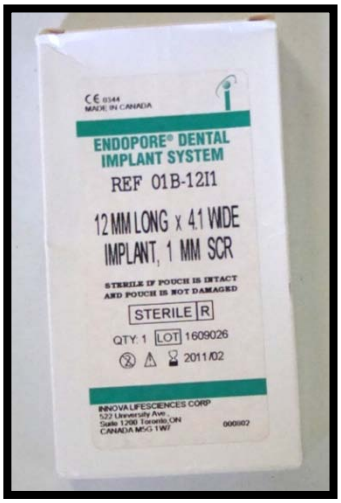
SIGNATURE OF THE H.O.D.

ARMAMENTARIUM

Surgical Instruments



Diagnostic Instruments



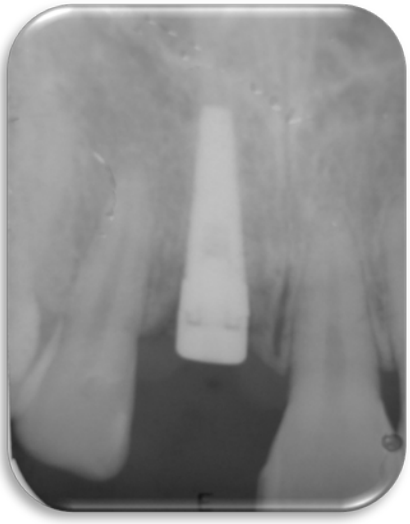
Endopore® Dental Implant

Endopore® Dental Implant Kit

NON AUGMENTED SITE

PRE OPERATIVE BASELINE CLINICAL AND RADIOGRAPH

3 MONTHS POST OPERATIVE



4.1mm x 12mm implant placed

6 MONTHS POST OPERATIVE

Healing satisfactory, picture showing Implant with gingival tissue former.

POST LOADING

clinical photograph and digitalized radiograph

showing acceptable esthetic outcome.

RESULTS

A total of 14 Dental implants were placed. Among them 7 implants were placed on pre-augmented sites and 7 implants were placed on non augmented sites. However one patient from the control group did not follow up hence was removed from the study.

The crestal bone levels were assessed on digitalized intra oral peri apical radiograph at 3rd month and 6th month follow-up periods.

STATISTICAL ANALYSIS

The Mean and Standard Deviation of the clinical probing depth, radiographic measurement of the crestal bone level and bone to implant contact at 3rd and 6th month period were analyzed using SPSS version 10.5 software.

The student t test was adopted to evaluate the significance of crestal bone level at different time period (3rd and 6th month) between both the groups.

INTERPRETATION OF RESULTS:

CLINICAL PARAMETERS:

WIDTH OF KERATINIZED GINGIVA

The mean width of keratinized gingiva in the mesial sides were **3.14, 3.29** and **3.14** while in distal sides they were **2.86, 3.0** and **2.86** respectively at baseline, 3rd month and 6th month**.**

At non augmented sites, the mean width of keratinized gingiva in the mesial side were **3.83** and **3.5** in the distal side throughout the study period.

GINGIVAL BIOTYPE

The mean gingival biotype were **1.86** and **1.67** at augmented and non augmented sites throughout the study period.

PAPPILA HEIGHT

The mean papilla height in the augmented mesial sides were **2.29, 2.29** and **2.71** while in distal side it remained **2.0** throughout the study period**.**

At non augmented sites, the papilla height in mesial sides were **3.12, 3.17** and **2.67** respectively and in distal sides readings were **2.67** throughout study period.

PROBING DEPTHS

The mean probing depths in the augmented mesial sides were **1.36, 1.5** and **1.64** while in distal sides they were **1.43, 1.43** and**1.57** at baseline 3rd month and 6th month respectively**.**

At non augmented sites, the probing depths in mesial sides were **1.25, 1.33**and **1.58** and in distal sides readings were **1.42, 1.42** and**1.58** at baseline 3rd month and 6th month respectively**.**

CRESTAL BONE LEVELS

The mean crestal bone levels in the augmented mesial sides were **2.5, 2.57** and **2.86** while in distal sides they were **2.43, 2.5** and **2.79** at baseline 3rd month and 6th month respectively**.**

At non augmented sites, the bone levels in mesial sides were **2.33, 2.33** and **2.58** and in distal sides readings were **2.42, 2.42** and **2.67** at baseline 3rd month and 6th month respectively**.**

BONE IMPLANT LEVELS

The mean bone implant levels in the augmented mesial sides were **0, 0.36** and **0.57** while in distal sides they were**0, 0.29** and **0.57** 3rd month and 6th month respectively**.**

At non augmented sites, the mean bone implant levels in mesial sides were **0, 0.5** and **0.67** and in distal sides readings were **0**, **0.5** and **0.58** 3rd month and 6th month respectively**.**

All the above parameter showed no clinical and radiographical differences at 3^{rd} and 6^{th} month, when compared. Statistical significant however the crestal bone level and bone implant level were statistically assessed using student t test using p value < 0.05 and confidence level at 95 % the results showed no statistically difference between the augmented and non augmented values at 3^{rd} and 6^{th} month

TABLE 1: PATIENT – IMPLANT DIMENSIONS

CASE NO	AGE	SEX	SITE	IMPLANT	
				DIAMETER	LENGTH
PATIENT 1	36	M	14	3.5	9
PATIENT 2	50	F	15	3.5	9
PATIENT 3	30	M	21	4.1	12
PATIENT 4	50	F	15	3.5	9
PATIENT 5	36	F	24	3.5	9
PATIENT 6	43	M	22	4.1	12
PATIENT 7	34	M	11	3.5	9
PATIENT 8	25	M	11	4.1	12
PATIENT 9	50	F	15	3.5	9
PATIENT 10	20	F	11	4.1	12
PATIENT 11	18	M	11	4.1	12
PATIENT 12	25	M	11	3.5	9
PATIENT 13	26	F	14	3.5	9
PATIENT 14	23	M	21	3.5	9

Shows the total of patients and the following implant dimensions. The patient no.1 to no.7 are socket augmented patients, the patient no.8 to no.14 are non augmented patients among which patient no.14 was excluded from the study.

TABLE 2a : WIDTH OF KERATINIZED GINGIVA – AUGMENTED SITE

NAME	WIDTH OF KERATIN MUCOSA					
	BASE M	**BASE D**	**3 MON M**	**3 MON D**	**6 MON M**	**6 MON D**
PATIENT 1	2	2	3	3	3	3
PATIENT 2	2	2	3	3	2	2
PATIENT 3	4	4	4	4	4	4
PATIENT 4	3	3	2	2	2	2
PATIENT 5	4	3	4	3	4	3
PATIENT 6	4	3	4	3	4	3
PATIENT 7	3	3	3	3	3	3
MEAN	3.14	2.86	3.29	3	3.14	2.86
SD	0.83	0.64	0.70	0.53	0.83	0.64

TABLE 2b : WIDTH OF KERATINIZED GINGIVA – NON AUGMENTED SITE

NAME	WIDTH OF KERATIN MUCOSA					
	BASE M	**BASE D**	**3 MON M**	**3 MON D**	**6 MON M**	**6 MON D**
PATIENT 8	5	5	5	5	5	5
PATIENT 9	3	2	3	2	3	2
PATIENT 10	4	4	4	4	4	4
PATIENT 11	4	5	4	5	4	5
PATIENT 12	4	3	4	3	4	3
PATIENT 13	3	2	3	2	3	2
MEAN	3.83	3.5	3.83	3.5	3.83	3.5
SD	0.69	1.26	0.69	2.52	0.69	1.26

TABLE 3a : GINGIVAL PHENOTYPE -AUGMENTED SITE

NAME	GINGIVAL BIOTYPE		
	BASELINE	**3 MON**	**6 MON**
PATIENT 1	2	2	2
PATIENT 2	2	2	2
PATIENT 3	2	2	2
PATIENT 4	2	2	2
PATIENT 5	2	2	2
PATIENT 6	1	1	1
PATIENT 7	2	2	2
MEAN	1.86	1.86	1.86
SD	0.35	0.35	0.35

TABLE 3b : GINGIVAL PHENOTYPE – NON AUGMENTED SITE

NAME	GINGIVAL BIOTYPE		
	BASELINE	**3 MON**	**6 MON**
PATIENT 8	2	2	2
PATIENT 9	2	2	2
PATIENT 10	1	1	1
PATIENT 11	1	1	1
PATIENT 12	2	2	2
PATIENT 13	2	2	2
MEAN	1.67	1.67	1.67
SD	0.47	0.47	0.47

TABLE 4a : PROBING DEPTH –AUGMENTED SITE

NAME	PROBING DEPTH					
	BASE M	**BASE D**	**3 MON M**	**3 MON D**	**6 MON M**	**6 MON D**
PATIENT 1	1.5	1	2	1	2	1
PATIENT 2	1	1.5	1	1.5	2	2
PATIENT 3	1.5	2	1.5	2	1.5	2.5
PATIENT 4	1	1.5	1	1.5	1	1.5
PATIENT 5	1	1	1.5	1	1.5	1
PATIENT 6	2	2	2	2	2	2
PATIENT 7	1.5	1	1.5	1	1.5	1
MEAN	1.36	1.43	1.5	1.43	1.64	1.57
SD	0.35	0.42	0.38	0.42	0.35	0.56

TABLE 4b : PROBING DEPTH– NON AUGMENTED SITE

NAME	PROBING DEPTH					
	BASE M	**BASE D**	**3 MON M**	**3 MON D**	**6 MON M**	**6 MON D**
PATIENT 8	1.5	1.5	2	1.5	2	1.5
PATIENT 9	1	1	1	1	1	1
PATIENT 10	1.5	1.5	1.5	1.5	2	2
PATIENT 11	1	1.5	1	1.5	1.5	2
PATIENT 12	1.5	2	1.5	2	1.5	2
PATIENT 13	1	1	1	1	1.5	1
MEAN	1.25	1.42	1.33	1.42	1.58	1.58
SD	0.25	0.34	0.37	0.34	0.34	0.44

TABLE 5a : CRESTAL BONE LEVEL – AUGMENTED SITE

NAME	CRESTAL BONE LEVEL					
	BASE M	**BASE D**	**3 MON M**	**3 MON D**	**6 MON M**	**6 MON D**
PATIENT 1	3	2.5	3.5	3	3.5	3
PATIENT 2	2	3	2	3	2	3
PATIENT 3	2.5	2	2.5	2	3	2.5
PATIENT 4	2.5	2	2.5	2	3	2.5
PATIENT 5	2	2	2	2	2.5	2.5
PATIENT 6	2.5	3	2.5	3	3	3.5
PATIENT 7	3	2.5	3	2.5	3	2.5
MEAN	2.5	2.43	2.57	2.5	2.86	2.79
SD	0.38	0.42	0.49	0.46	0.44	0.36

TABLE 5b : CRESTAL BONE LEVEL – NON AUGMENTED SITE

NAME	CRESTAL BONE LEVEL					
	BASE M	**BASE D**	**3 MON M**	**3 MON D**	**6 MON M**	**6 MON D**
PATIENT 8	3	3	3	3	3.5	3.5
PATIENT 9	2	2	2	2	2	2
PATIENT 10	3	2.5	3	2.5	3.5	3
PATIENT 11	2	3	2	3	2	3
PATIENT 12	2	3	2	3	2.5	3.5
PATIENT 13	2	1	2	1	2	1
MEAN	2.33	2.42	2.33	2.42	2.58	2.67
SD	0.47	0.73	0.47	0.73	0.67	0.90

TABLE 6a : IMPLANT BONE LEVEL– AUGMENTED SITE

NAME	BONE IMPLANT LEVEL					
	BASE M	**BASED**	**3 MON M**	**3 MON D**	**6 MON M**	**6 MON D**
PATIENT 1	0	0	1	1	1	1
PATIENT 2	0	0	0	0	1	1.5
PATIENT 3	0	0	0.5	0	0.5	0
PATIENT 4	0	0	0	0	0.5	0.5
PATIENT 5	0	0	0	0	0	0
PATIENT 6	0	0	0.5	0.5	0.5	0.5
PATIENT 7	0	0	0.5	0.5	0.5	0.5
MEAN	0	0	0.36	0.29	0.57	0.57
SD	0	0	0.35	0.36	0.32	0.50

TABLE 6b : IMPLANT BONE LEVEL– NON AUGMENTED SITE

NAME	BONE IMPLANT LEVEL					
	BASE M	**BASED**	**3 MON M**	**3 MON D**	**6 MON M**	**6 MON D**
PATIENT 8	0	0	0.5	0.5	0.5	0.5
PATIENT 9	0	0	0.5	0.5	1	0.5
PATIENT 10	0	0	0.5	0.5	0.5	1
PATIENT 11	0	0	1	0.5	1.5	0.5
PATIENT 12	0	0	0.5	0.5	0.5	0.5
PATIENT 13	0	0	0	0.5	0	0.5
MEAN	0	0	0.5	0.5	0.67	0.58
SD	0	0	0.29	0	0.47	0.19

TABLE 7a : PAPILLA HEIGHT- AUGMENTED SITE

NAME	PAPILLA HEIGHT					
	BASE M	BASE D	3 MON M	3 MON D	6 MON M	6 MON D
PATIENT 1	2	3	2	3	3	3
PATIENT 2	1	1	1	1	2	1
PATIENT 3	3	3	3	3	4	3
PATIENT 4	1	1	1	1	1	1
PATIENT 5	3	1	3	1	3	1
PATIENT 6	2	1	2	1	2	1
PATIENT 7	4	4	4	4	4	4
MEAN	2.29	2	2.29	2	2.71	2
SD	1.03	1.20	1.03	1.20	1.03	1.20

TABLE 7b : PAPILLA HEIGHT – NON AUGMENTED SITE

NAME	PAPILLA HEIGHT					
	BASE M	BASE D	3 MON M	3 MON D	6 MON M	6 MON D
PATIENT 8	3	3	3	3	3	3
PATIENT 9	2	2	2	2	2	2
PATIENT 10	4	3	4	3	3	3
PATIENT 11	3	2	3	2	2	2
PATIENT 12	4	3	4	3	3	3
PATIENT 13	3	3	3	3	3	3
MEAN	3.12	2.67	3.17	2.67	2.67	2.67
SD	0.69	0.47	0.69	0.47	0.47	0.47

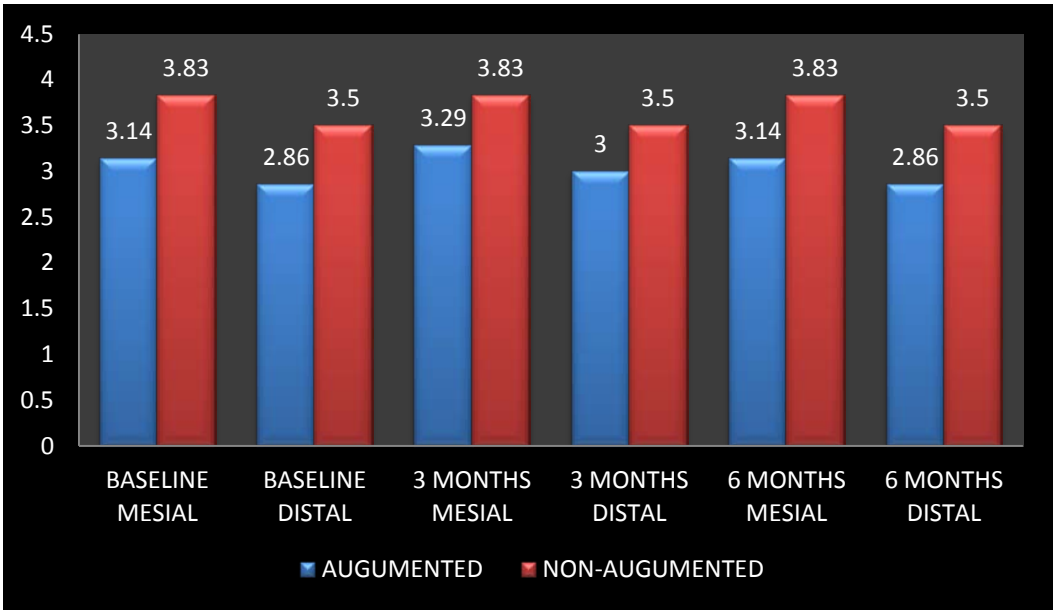
TABLE 8a : COMPARING AUGMENTED GROUP VS NON AUGMENTED GROUPS - MESIAL VALUES

PARAMETERS	**CBL**				**IBL**			
DURATION	3^{RD} MONTH		6^{TH} MONTH		3^{RD} MONTH		6^{TH} MONTH	
GROUP	TEST	CON	TEST	CON	TEST	CON	TEST	CON
MEAN	0.007	0.000	0.357	0.250	0.357	0.500	0.571	0.667
SD	0.018	0.000	0.244	0.274	0.378	0.316	0.345	0.516
P VALUE	0.377		0.471		0.480		0.699	

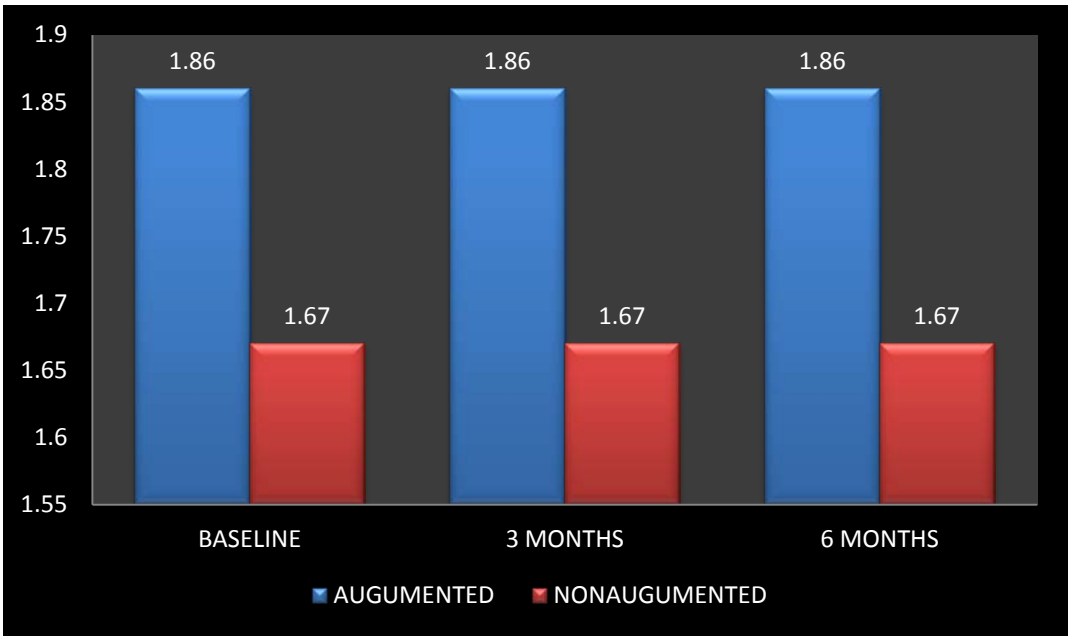
TABLE 8b : COMPARING AUGMENTED GROUP VS NON AUGMENTED GROUP - DISTAL VALUES

PARAMETERS	**CBL**				**IBL**			
DURATION	3^{RD} MONTH		6^{TH} MONTH		3^{RD} MONTH		6^{TH} MONTH	
GROUP	TEST	CON	TEST	CON	TEST	CON	TEST	CON
MEAN	0.071	0.000	0.357	0.250	0.286	0.500	0.571	0.583
SD	0.189	0.000	0.357	0.274	0.393	0.000	0.535	0.204
P VALUE	0.377		0.471		0.212		0.212	

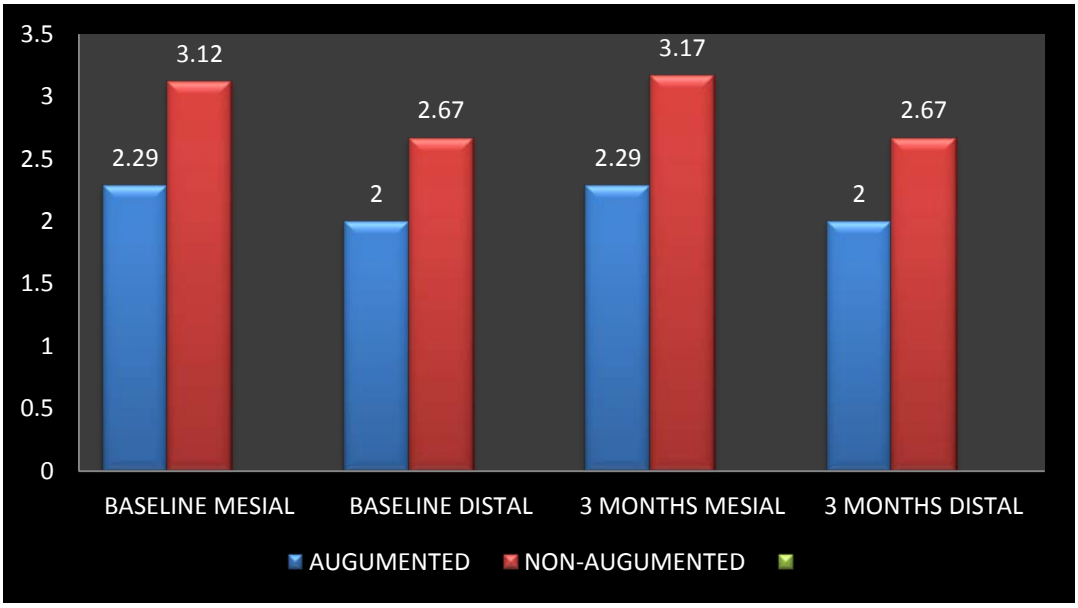
Graph 1: THE WIDTH OF KERATINIZED GINGIVA AT BASELINE, 3 MONTHS AND 6TH MONTHS



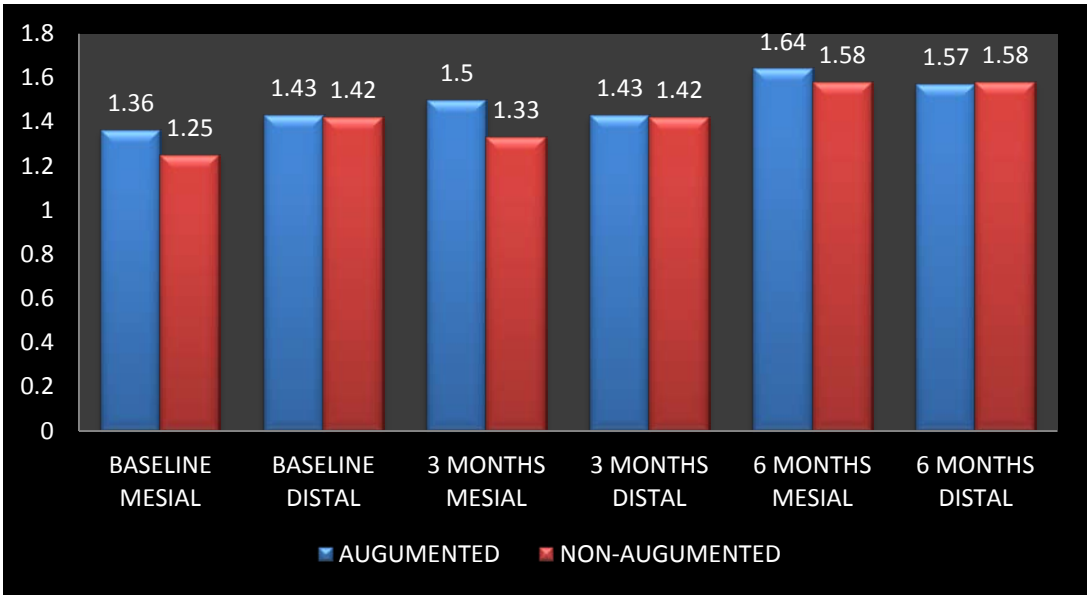
Graph 2: THE GINGIVAL PHENOTYPE AT BASELINE, 3MONTHS AND 6TH MONTHS



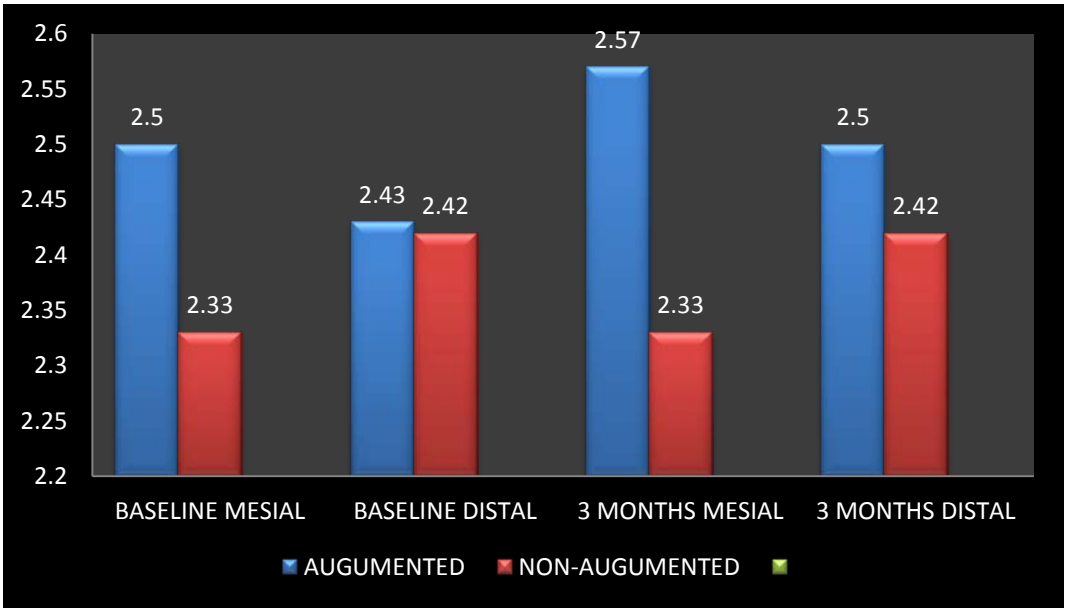
Graph 3 : THE PAPILLA HEIGHT AT BASELINE, 3MONTHS AND 6TH MONTHS



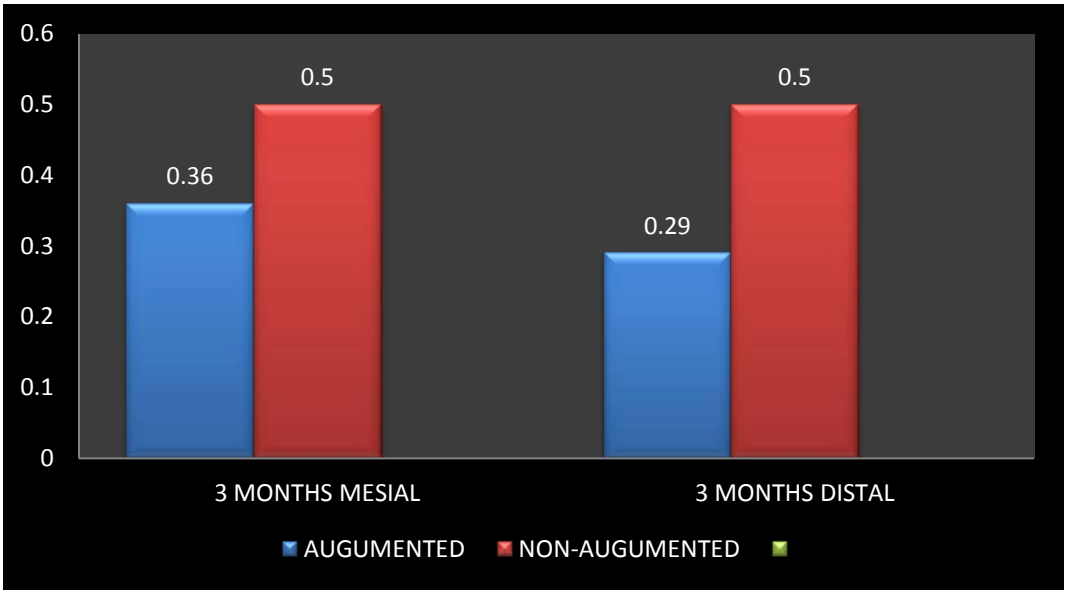
Graph 4 : THE ADJACENT PROBING POCKET DEPTH AT BASELINE, 3MONTHS AND 6TH MONTHS



Graph 5 : THE CRESTAL BONE LEVEL AT BASELINE, 3 MONTHS AND 6TH MONTHS



Graph 6 : THE IMPLANT BONE LEVEL AT BASELINE, 3 MONTHS AND 6TH MONTHS



DISCUSSION

The quality and quantity of bone are known to be an important determinant of implant stability. In critical areas like the anterior maxilla, the residual ridge both hard and soft tissue also plays an important role in the esthetic outcome of implant supported prosthesis.[1]The anterior maxilla is often deficient in both horizontal and vertical dimensions. This deficiency may be either due to the traumatic episode, endodontic complication or periodontal bone loss that may have led to the tooth extraction. Iatrogenic injury to the labial plate at the time of extraction is another contributory factor to the ridge deficiency. [33]

This hard tissue loss is often accompanied by the changes in the soft tissue architecture. These changes are more pronounced in patients with a thin gingival phenotype or inadequate width of keratinized gingiva. Previous studies by Vandana et al. (2005)[46] have indicated that there is considerable racial variation in gingival phenotype and among various population and ethnic groups. Consequently, there is often a need for ridge preservation or augmentation prior to implant placement for both functional and esthetic needs.

The fate of the bone replacement graft placed into the extraction socket has been a subject of much speculation in

periodontal literature. A study by Clark et al. (1988)[21] has reported that graft particles undergo fibrous encapsulation, which leads to poor integration into the native bone. There has also been much debate over the functionality of the newly formed bone in terms of its turnover rate and remodeling.[39, 21]

A systematic review by Donald et al. (2005)[29] have, however, suggested that regardless of the type of bone replacement graft used and the surgical procedure followed a loss of 1to1.5mm of labial crestal bone is almost invariably observed.

The present study was therefore undertaken to evaluate the crestal hard and soft tissue following implant placement in previously augmented and non-augmented sites. In this study the augmented sites were treated with a xenograft collagen combination. Implant placement was done after 6 months in all augmented sites.

There has been conflicting literature regarding the Xenograft used in this study. A Study by Hunt and Heppenstall (1984)[43] had reported fibrous encapsulation or formation of a mineralized tissue which may not be identical to native bone, while the study by Molly and Vandromme (2008)[53] reported that there is new bone formation around the grafted particles with adequate volume of bone formed over a period of time.

In our study one site that was planned for implant placement showed fibrous encapsulation that was observed in the radiographs and clinically during implant placement. However as this encapsulation occurred labial to site of osteotomy it did not interfere with either the implant placement or its survival. None of the other cases in the test group showed evidence of either residual graft particles or areas of fibrous tissue, atleast in the osteotomy site.

The placement of sintered porous surfaced dental implants differs from that of the threaded implant.[25] A standardized methodology was followed for implant placement in the augmented and non-augmented sites. The crestal incisions were placed slightly palatal in order to preserve as much of the keratinized tissue as possible. The drilling sequence was followed as per the recommendations but prior to the insertion of the ENDOPORE® implant the firm adaptation of its trial fit gauge was assessed. This was used to identify the appropriate initial stability of the implant to be placed in a press-fit manner.

None of the patients reported with evidence of any post operative complications in the implant site during or after placement of the same. All assessments were made following one month of the placement. The width of the keratinized gingival tissue was measured to identify if the surgical procedure that involved flap

displacement had any effect on the width of the keratinized tissue. The results of this study showed that there was no differences in the width of the keratinized gingiva when assessed pre operatively and post operatively in both test and control groups. This result indicates that the surgical protocol that was followed in this study for the initial socket augmentation and implant placement in both the groups resulted in no loss of keratinized tissue. This was probably because all incisions were made not at the mid crestal region, but slightly palatal so as to allow a tension free primary closure, preserving as much of the keratinized gingiva as possible. The measurements recorded at the 3^{rd} and 6^{th} month follow up showed no change as the width of keratinized tissue remained the same throughout the study period.

Gingival phenotype is thought to exert considerable influence on the regenerating site.[72] The majority of the patients included in our sample consisted of thick phenotype to prevent increase graft/membrane exposure in the augmenting socket. There was no statistically significant difference between the gingival phenotype between the two groups. However, in two patients from the control group and one patient in the test group with thin phenotype, the metallic hue of the implant collar was clearly visible because of the translucency of the gingiva. This number was too small to attain statistically significance. These results suggest that thin gingival phenotype may contribute to compromised esthetics in the anterior

maxillary segment. This result is in agreement with a previous study by Kois et al. (2001).[48]

There was no statistical significant difference between the test and the control groups in terms of the crestal bone level at mesial, mid-buccal and distal sites when measured against adjacent cemento-enamel junction at the baseline. Any difference in the labial crest during the subsequent measurement could thus be attributed to the quality of the mineralized tissue that has formed in the augmented sites. However the results of the present study showed that there is no difference in the level of the labial bone at 3rd and 6th month follow up period. These results are in agreement with a previous study by Grunder et al. (2005).[34]

The ridge form obtained in both group appeared conducive to esthetic outcome following implant placement. No significant difference was observed between in the two groups. A more detailed soft tissue assessment with respect to the interdental papilla could not be undertaken as the study did not include assessment post loading.

These results suggest that there were no significant differences in the hard and soft tissue behavior following implant placement in the socket augmented and non augmented sites. These

results are in overall agreement with a study by Fritz et al. (2001),[31] but contrary to those by Zafiropoulos et al. (2010).[77]

The limitations of this study included a small sample size and the short period of investigation. Further, bone behavior could have been more meaningfully assessed if we had assessed the socket preserved sites against immediate implant placed with more number of cases and with longer follow up.

SUMMARY AND CONCLUSION

The study titled “clinical and radiographic assessment of socket augmented and non augmented sites restored using sintered porous surface dental implant (Endopore®) in maxillary single edentulous site - a comparative study” enrolled 14 patients seeking replacement of maxillary single edentulous site with Dental implant. Among them 7 patients had previously augmented sites (atraumatic extraction followed by socket augmentation) were taken as test group and 7 patients with adequate non augmented sites were involved in the study.

However one patient from the control group could not continue with regular follow up and hence was excluded from the study.

After administration of local anesthesia and alveolar crest exposure, the osteotomy site was prepared, followed by sequential drilling up to the final drill and following the confirmation of trial fit gauge Dental ENDOPORE® implant was placed.

The patients were evaluated at 3rd and 6th month period for width of keratinized gingiva, gingival phenotype and the crestal bone level both clinically and radiographically.

Within the limits of this study, the following conclusions have been elucidated:

1. There is no difference in the peri implant soft tissue of socket augmented and non augmented maxillary single edentulous sites following restoration using sintered porous surfaced dental implant ENDOPORE®.
2. There is no difference in the peri implant hard tissue parameter of socket augmented and non augmented maxillary single edentulous sites following restoration using sintered porous surfaced dental implant ENDOPORE®.
3. Even though this method of augmenting the extracted socket followed by delayed 2 staged procedure, it produces promising results which are comparable to non augmented native sites

Thus, it is appropriate to conclude that, the socket augmented implant sites have obvious advantages over non augmented or immediate implant placement were labial plate resorption is in evitable. Hence one must consider preserving the maximum socket walls by atraumatic extractions followed by socket augmentation when ever Dental implants are indicated

However, further controlled clinical trials with larger sample size, split mouth study design would be more appropriate to elucidate the difference between augmented and non augmented peri implant sites.

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